IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

CHERYL MOULTRIE and PETER MOULTRIE, Plaintiffs,	)	
vs	)	Civil Action No. 18-231
	)	Magistrate Judge Dodge
COLOPLAST CORP. and COLOPLAST MANUFACTURING US, LLC, Defendants.	)	

MEMORANDUM OPINION

Plaintiffs, Cheryl Moultrie and her husband, Peter Moultrie, bring this action in which they assert strict liability and negligence claims against Defendants Coloplast Corp. and its wholly-owned subsidiary, Coloplast Manufacturing US, LLC (together, "Coloplast"). Plaintiffs' claims arise out of injuries that they allegedly sustained as a result of a product designed and manufactured by Coloplast.

Currently pending before the Court for disposition is Coloplast's motion for summary judgment. For the reasons that follow, Coloplast's motion will be granted with respect to the claims related to manufacturing defects that were asserted under theories of strict liability (in Count I) and negligence (in Count III), and otherwise denied.

I. Relevant Procedural History

Plaintiffs commenced this action in February 2018 against Coloplast and Mentor Worldwide, LLC.[1] Subject matter jurisdiction is based on diversity of citizenship and the amount in controversy exceeds the sum of $75,000, exclusive of interest and costs. (Compl. ¶¶ 1-15.)[2] Counts I through XIII of the Complaint asserts various causes of action by Mrs. Moultrie and

[1] Mentor was voluntarily dismissed on March 26, 2018 (ECF No. 4).
[2] ECF No. 1.

Count XIV sets forth a claim of loss of consortium by Mr. Moultrie.

On September 20, 2018, the parties consented to have this case heard before a United States Magistrate Judge (ECF No. 41) and the case was assigned to Magistrate Judge Mitchell. Following Judge Mitchell's retirement, the case was reassigned to the undersigned.

The parties entered into a Stipulation of Partial Dismissal (ECF No. 59), which was granted by the Court on July 22, 2019. Pursuant to the parties' agreement, Counts IV through XI and XIII were dismissed (ECF No. 60). In response to the pending motion for summary judgment, Plaintiffs indicate that they are no longer pursuing their manufacturing defect claims (portions of Counts I and III) or their cause of action for gross negligence (Count XII). (ECF No. 78 at 1.)[3]

Therefore, the remaining causes of action in this action are for strict liability based upon a design defect (Count I) and failure to warn (Count II), negligent design and failure to warn (Count III) and loss of consortium (Count XIV).

II. Relevant Factual Background

A. Mrs. Moultrie's Surgery

On May 21, 2010, Mrs. Moultrie (then Cheryl Smith) underwent pelvic reconstructive surgery that was performed by Jeffrey David, M.D at Armstrong County Memorial Hospital in Kittanning, Pennsylvania. During this procedure, Dr. David implanted Coloplast's Aris Transobturator Sling System ("Aris") to treat her stress urinary incontinence ("SUI"). (Defendants' Concise Statement of Material Facts ("DCSMF") ¶ 1.)[4] The Aris is an FDA-cleared, prescription-only surgical mesh implant indicated for pelvic-floor reconstructive surgery

[3] While Plaintiffs suggest that as to these claims, Coloplast's motion should be denied as moot, they cite no authority for this approach. Rather, since Plaintiffs have not opposed Coloplast's motion as to these claims, Coloplast's motion will be granted.
[4] ECF No. 65.

but has not been subjected to FDA pre-market approval. (DCSMF ¶ 2; Plaintiffs' Response to Defendants' Concise Statement of Facts ("PCSMF") ¶ 2[5]). The Aris was indicated for the procedure used by Dr. David to treat Mrs. Moultrie's SUI. (*Id.*) While Dr. David still offers the Aris as a surgical treatment option to appropriate patients in order to treat female SUI and is aware of risks associated with its use, the hospital, not Dr. David, chooses the devices that are used in its facility. (*Id.* ¶ 3.)

Based on his concerns regarding the safety and efficacy of alternative procedures—so-called "native tissue repairs" or surgical procedures that do not employ surgical mesh to treat SUI—Dr. David does not perform those procedures on his patients, nor would he have elected to do so in his treatment of Mrs. Moultrie in May of 2010. (DCSMF ¶ 11.) Instead, Dr. David would refer patients who did not want to have a mesh procedure to other doctors. (PCSMF ¶ 11.)

Coloplast issues "Instructions for Use" ("IFU") for the Aris sling, which includes a recitation of potential risks and complications related to its use. (*See, e.g.,* DCSMF ¶ 10; PCSMF ¶¶ 61, 62, 79,80.) According to Dr. David, there are risks associated with the surgery itself, which include excessive bleeding, infection and exposure of the tape. (PCSMF ¶ 4.) It is his practice to always inform his patients of the possibility that after undergoing pelvic-floor reconstructive surgery with the Aris, they may also develop dyspareunia (painful sexual intercourse), pelvic pain and urinary dysfunction, and that they may experience an erosion or exposure. (DCSMF ¶ 4.) These risks are identified in Coloplast's IFU. Dr. David was unaware of a risk of permanent dyspareunia and did not inform his patients of such a risk. (PCSMF ¶ 4.) He acknowledges that implantation of the Aris was "elective surgery," not "emergency surgery," and "[i]f there was an extraordinary risk, [he] would be obliged to mention it" to his patients. (*Id.*

[5] ECF No. 79.

¶ 78.)

Dr. David tells his patients that in the vast majority of cases, the SUI is completely resolved, but a small number of patients will still experience some SUI, although not to the same degree as before the surgery. (David Dep. 51:9-19.)[6] He also informs them that, as with any surgery, there is a possibility of complications that may require another surgery. (*Id.* at 52:5-12.) It is also Dr. David's practice to inform his patients that while the Aris is intended to be a permanent implant, it may need to be removed "at some point for some reason." (DCSMF ¶ 6.)[7]

Dr. David had read the IFU several times roughly six years prior to Mrs. Moultrie's surgery. (PCSMF ¶ 10; see David Dep. 55:19-56:3, 135:15-19.) However, he had "[n]o recollection" of reviewing the Aris IFU before performing her May 21, 2010 pelvic reconstructive surgery and denies relying on the Aris IFU in order to perform that procedure. (DCSMF ¶ 10.) Dr. David was bothered by the general warnings in the IFU, which did not address the specific risks associated with the Aris sling:

> A. It's speaking in general terms, which bothers me. "Known risks of incontinence surgical procedures include the following." They're not saying of the TOT, but they are saying that incontinence procedures, which includes all the ones we talked about, can do that.

(PCSMF ¶ 80.)

Dr. David has no general recollection of Mrs. Moultrie. (PCSMF ¶ 7.) When asked

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[6] Defs.' App. (ECF No. 66) Ex. 3.

[7] In response to this statement of fact and many others, Plaintiffs stated: "Denied as stated. It is admitted that [X's] testimony speaks for itself." If Coloplast misstated a witness's testimony, Plaintiffs may deny the statement and correct the record. If Coloplast has accurately cited to the record, however, the appropriate response is "admitted." Similar to Plaintiffs, Coloplast responds to many of Plaintiffs' statements of fact by simply saying "denied" or "denied as stated" without citing to any record evidence to the contrary. Pursuant to this Court's Local Rules, a party must set forth the basis for a denial with appropriate reference to the record. LCvR 56.C(1)(b). Simply put, a mere denial does not create an issue of fact.

whether he had informed Mrs. Moultrie of the risks associated with the Aris, Dr. David responded "Yes, as a routine." (*Id.* ¶ 7.) On May 18, 2010, after consulting with Dr. David about the potential risks of using the Aris, Mrs. Moultrie gave her informed consent to proceed with the surgery. (DCSMF ¶¶ 8-9.) Dr. David stated that he implanted the Aris mesh device correctly as he was trained to do. (PCSMF ¶ 77.)

If Coloplast had communicated percentages of risks on the various complications that could occur, Dr. David would have presented those percentages to his patients, including Mrs. Moultrie, so that she could make an informed decision. (PCSMF ¶ 81.) Mrs. Moultrie testified that if she had been informed of the true risks associated with the Aris, such as permanent vaginal pain, permanent pelvic pain, and permanent dyspareunia, she would not have consented to the Aris implantation surgery. (*Id.* ¶ 82.)

B. Mrs. Moultrie's Subsequent Condition and Treatment

On December 2, 2015, Mrs. Moultrie was involved in a motor-vehicle accident "at a high (45 miles an hour) speed." (DCSMF ¶ 13.) The airbags in her SUV did not deploy and she suffered no broken bones, sprains, or bleeding. While she did not go to the emergency room immediately after the accident, she did so later that day, complaining of neck pain. (PCSMF ¶ 13.)

Two weeks later, on December 17, 2015, Mrs. Moultrie returned to the Emergency Department at Lee Memorial Health System with complaints of hematuria (blood in her urine); she also reported "pass[ing] a quarter-sized blood clot in the toilet earlier" that day and that she experienced worsening incontinence after her motor vehicle accident. (DCSMF ¶ 14.) However, Mrs. Moultrie had already been experiencing worsening incontinence since February 13, 2015, or ten months before the auto accident. (PCSMF ¶ 14.)

On August 24, 2017, Dr. Eric Gwynn performed a surgical removal of Mrs. Moultrie's Aris at Coastal Carolina Medical Center. (DCSMF ¶ 17.) Dr. Gwynn's removal surgery was indicated primarily due to erosion of the Aris into Mrs. Moultrie's urethra. (*Id.* ¶ 18.) It was medically necessary to excise the Aris because of this erosion and the fact that Mrs. Moultrie had calcification into her urethra, worsening leakage, and recurrent urinary tract infections. (PCSMF ¶ 84.) Dr. Gwynn first visualized this erosion during a cystoscopy he performed on August 15, 2017 that was indicated due to Mrs. Moultrie's complaints of recurrent urinary incontinence, which she said had been "progressively worsening" since her December 2, 2015 car accident. (DCSMF ¶¶ 19, 20.) Dr. Gwynn also indicated Mrs. Moultrie's dystrophic calcification was caused by the Aris erosion. (*Id.* ¶ 89.) According to Dr. Gwynn, the erosion attributed to the Aris was "fairly large," approximately "50 percent posteriorly." (*Id.* ¶ 91.)

Once placed, the Aris can be difficult, if not impossible, to fully remove because the patient's tissues grow around it. (PCSMF ¶ 85.) Even after Mrs. Moultrie's Aris removal procedure, she still has some sling material in her pelvic tissues. (*Id.* ¶ 86.)

Dr. Gwynn initially documented in his records that he did not think that the erosion was the result of her motor vehicle accident in 2015. (DCSMF ¶ 21.) At the time he made that assessment, however, he did not have "any details of the accident," nor did he have any knowledge "about the forces involved in that accident." (DCSMF ¶ 22.) Now, Dr. Gwynn cannot "definitely say that that accident didn't have something to do with her erosion and that he "can't rule [the accident] out" as a cause of her urethral erosion. (DCSMF ¶23.) At the same time, however, Dr. Gwynn has never seen mesh erosion caused by a low-impact car accident and he finds it "bizarre that a deceleration injury could cause that erosion. "(PCSMF ¶¶ 22-23, 90.)

Mrs. Moultrie's current complaints include dyspareunia, pelvic pain, incontinence and urinary tract infections. Plaintiffs assert that their injuries and damages are directly attributable to the defective design of the Aris and Coloplast's failure to warn them of the risks and complications of its use.

C. Design of the Aris

Although the Aris is a heavyweight, small-pore mesh[8], Coloplast knew that lighter weight mesh alternatives existed prior to November 2008. (PCSMF ¶¶ 71-72.) At a 2008 Woman's Health Advisory Board Meeting, several doctors warned Coloplast about the use of heavier weight mesh and its relationship to increased erosion rates. (*Id.* ¶ 74.)

Plaintiff's general causation expert, Bruce Rosenzweig, M.D., has offered expert opinions and testimony about the dangers of the heavy-weight, small pore polypropylene mesh used by Coloplast, explaining:

> With heavy-weight, small pore mesh, "[y]ou get the same degree of chronic foreign body reaction, the same degree of chronic inflammation, the same degree of scar plating, the same degree of contraction, deformation, degradation, nerve entrapment, the same degree of pain of the meshes that were used 30 years ago. Those are the characteristics of your device – excuse me – your client's devices that make them unreasonably dangerous.

(*Id.* ¶ 73.) Dr. Rosenzweig was asked if he knew of any midurethral slings with lower density than the Aris and he indicated that he could think of only one. (DCSMF ¶ 33.) He stated that the Aris has a pore size of "330 microns." (*Id.* ¶ 34.)[9]

According to Dr. Rosenzweig, alternative and safer designs to the Aris are available, including an autologous fascia sling, the Burch colposuspension, an allograft sling such as

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[8] Coloplast denies this statement, which Plaintiffs have taken from the expert report of Dr. Rosenzweig, but cite no record evidence to rebut it.

[9] Defendants further assert that the Aris is an "Amid Type I, microporous surgical mesh implant" but as Plaintiffs note, Dr. Rosenzweig did not testify to this effect.

Repliform, and the Ultrapro, a surgical mesh device.

In Dr. Rosenzweig's expert report, he states that the Allograft has advantages compared to "synthetic material." Further, absorbable mesh "avoids the complications" (such as excessive scar tissue, urethral obstruction, and erosion) associated with non-absorbable mesh. (PCSMF ¶ 40.) He opines in his report that "[a]n absorbable section 'avoids the complications due to urethral erosion, vaginal erosion, urethral obstruction, [and] urinary retention.'" (*Id.* ¶ 41.)

One of Dr. Rosenzweig's alternative designs to the Aris, a lightweight, large-pore mesh like that used in the Ultrapro, has been studied for use in the treatment of stress incontinence in women. A study by Okulu et al. found that "Ultrapro mesh can be used in sling surgery owning to its higher success rates, and lower vaginal and urethral extrusion and de novo urgency rates…"[10] According to Dr. Rosenzweig, another alternative to the Aris is a Burch colposuspension, which uses a suture medical device. (PCSMF ¶¶ 75-76.)

Coloplast takes issue with Dr. Rosenzwieg's conclusion that any these devices are alternatives to the Aris sling. It contends that the autologous fascia sling is "not a medical device made from polypropylene," that the Burch colposuspension is "a surgical procedure that uses sutures," that "an allograft sling such as Repliform" is also "not made of polypropylene," and that the Ultrapro is a surgical mesh device indicated for repairing hernias and pelvic organ prolapse, not female SUI. (*Id.* ¶¶ 36-39.) In turn, Plaintiffs assert, among other things, that the Ultrapro device has been studied for use in treating SUI, and "can be used in sling surgery owing to its higher success rate, and lower vaginal and urethral extrusion and de novo urgency rates, which have also been shown in clinical studies." (PCSMF ¶¶ 37, 39.)

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[10] Coloplast contends that the Ultrapro has not been approved by the FDA for treatment of SUI. This issue is discussed below.

D. Risks Associated with the Aris

According to Dr. Rosenzweig, Coloplast failed to include in its IFU significant risks related to the Aris. This includes injury in the form of "life-long, late infections," as well as the fact that implantation through and into the non-sterile vagina is below the standard of care for any surgical technique, especially one used to treat non-life-threatening conditions such as SUI. (PCSMF ¶ 61.) Dr. Rosenzweig further opines that Coloplast's IFUs did not include sufficient information to advise physicians on the permanence, frequency, and severity of the complications that can arise from the use of its devices. Some of these complications include the injuries that Mrs. Moultrie claims to have experienced: chronic and debilitating pelvic pain, chronic dyspareunia, rejection of the mesh, sexual dysfunction, and the need for additional surgeries. (*Id.* ¶¶ 62-63.)[11]

Plaintiffs contend that Coloplast knew on or before November 2007 that the Aris had a complication rate as high as 8.5% for erosions/extrusions, and this information was never disclosed to treating physicians. (*Id.* ¶ 66.) Coloplast counters that this is irrelevant given the fact that Dr. David did not rely on the IFU and testified "elsewhere" that the existence of "two studies" that show only "seven patients" out of a total of "118 women" experienced erosions or extrusions "wouldn't keep [him] from offering the" Aris as a surgical treatment for female SUI. (Defendants' Reply to Plaintiffs' Response to Defendant's Concise Statement of Material Facts ("DRCSMF") ¶ 66.)[12]

As recently as 2013, Coloplast's consultants expressed concerns about safety issues associated with the Aris. Internal company documents and company witnesses confirm that

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[11] Coloplast takes the position that these statements are immaterial because Dr. David testified that he did not review or rely on the IFU prior to the surgery. This issue is discussed at a later point in this opinion.

[12] ECF No. 86.

Coloplast knew of the risks and complications associated with the Aris yet continued to market and sell the device to increase corporate profits. (PCSMF ¶¶ 64-65.) Coloplast acknowledged that it had a "strategic opportunity to own 'gold standard' mini-sling intellectual property," yet failed to implement these alternative designs which had the potential to reduced or eliminate adverse risks to patients. (*Id.* ¶ 69.)

Plaintiffs claim that in addition to concealing certain known risks, Coloplast significantly downplayed the risks that it actually listed in its IFU. In fact, according to Plaintiffs, the effects of chemical and biological degradation of the mesh in a woman's tissues can lead to a greater foreign body reaction, enhanced inflammatory response, and excessive scarring, which can lead to severe complications in patients. (PCSMF ¶¶ 67-68, 70.) Coloplast notes, however, that the pathologist who performed a gross examination of the portions of Mrs. Moultrie's Aris that were removed in August 2017 did not document evidence of any such "degradation." (DRCSMF ¶ 68, 70.)

E. Causation Opinions Expressed by Dr. Campbell

Grant Campbell, M.D., Plaintiffs' causation expert, initially opined that "Mrs. Moultrie's worsening stress urinary incontinence, pelvic pain, painful intercourse, and frequent urinary tract infections were caused by the defective Aris bladder neck suspension mesh." Subsequently, after reviewing additional records and information, Dr. Campbell withdrew his opinions that Mrs. Moultrie's pelvic pain and ongoing urinary urgency issues were caused by the Aris. (DCSMF ¶¶ 51-53.) He continues to stand by his remaining opinions.

The basis of Dr. Campbell's opinion that Mrs. Moultrie's current dyspareunia complaints were caused by her Aris was that he could "find no pre-operative clinical documentation of dyspareunia pre-dating" the Aris implant, and that he was able to recreate her pain at the "mesh

area" on examination. (*Id.* ¶ 54.) Dr. Campbell stated in his physical examination note that there were "[n]o other findings on physical exam [which would] suggest an alternative etiology for her discomfort and urinary leakage" other than the Aris. (PCSMF ¶ 88.)

At his May 24, 2019 deposition, Dr. Campbell was shown documentation from Mrs. Moultrie's medical records that revealed a pre-implant history of dyspareunia. (DCSMF ¶ 55.)[13] Coloplast argues that because Dr. Campbell did not know about that pre-existing history of dyspareunia, he is unable to dispute, with any degree of medical certainty, that the pain he reproduced on examination could have been of the same type, of the same degree, and in the same location as the dyspareunia that Mrs. Moultrie had experienced before May 20, 2010. (DCSMF ¶ 56.) However, Dr. Campbell remains "quite comfortable [saying] that it's related to her mesh complication." (Campbell Dep. 85:24-25.)[14] See also Second Addendum at 2 ("I feel that her continued dyspareunia issues as well as urinary tract infections can be related to her TOT complications with a reasonable degree of medical certainty. Likewise, the return of her stress urinary incontinence can be attributed to her TOT complications as well.")

Coloplast also notes that Dr. Campbell did not review any medical records relating to Mrs. Moultrie's car accident. Instead, he relied on Dr. Gwynn's August 2017 conclusion that her accident was not related to her complaints. (DCSMF ¶¶ 57-58.) Dr. Campbell's written report notes that he "cannot think of any reasonable explanation where [Mrs. Moultrie's December 2015] car accident would have caused this erosion" and that his second addendum further states that he had not found any "documentation that would make [him] disagree with Dr. Gwynn that her motor vehicle accident was not a contributing factor to her return of urinary incontinence."

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[13] Plaintiffs note that what Dr. Campbell was shown was a patient-completed form and that no doctor diagnosed Mrs. Moultrie with dyspareunia prior to her implant surgery. (PCSMF ¶ 55.)
[14] ECF No. 66 Ex. 10.

During his deposition, Dr. Campbell was asked about this issue. He confirmed that he relied upon Dr. Gwynn's findings that "the eroded sling was not caused by the accident." He also testified that for trauma to cause erosion, there must be an event that impairs vascular integrity, and he is not aware of any event that would cause devascularization in that area as a result of a motor vehicle accident. (*Id.* ¶¶ 59-60.)[15]

III. Discussion

A. Standard of Review

Pursuant to the Federal Rules of Civil Procedure, summary judgment is appropriate if there are no genuine disputes as to any material fact and the moving party is entitled to judgment as a matter of law. Fed.R.Civ.P. 56(a). Summary judgment may be granted against a party who fails to adduce facts sufficient to establish the existence of any element essential to that party's case, and for which that party will bear the burden of proof at trial. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). The moving party bears the initial burden of identifying evidence which demonstrates the absence of a genuine issue of material fact. Once that burden has been met, the non-moving party must set forth "specific facts showing that there is a genuine issue for trial" or the factual record will be taken as presented by the moving party and judgment will be entered as a matter of law. *Matsushita Elec. Indus. Corp. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986). An issue is genuine only if the evidence is such that a reasonable jury could return a verdict for the nonmoving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). The Court of Appeals has held that "where the movant bears the burden of proof at trial and the motion does

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[15] Coloplast suggests that because Dr. Gwynn subsequently testified that he cannot rule out the car accident as a cause of Mrs. Moultrie's urethral erosion, Dr. Campbell's opinion necessarily would change. Dr. Campbell has not modified his opinion in this regard, however, as his testimony confirms.

not establish the absence of a genuine factual issue, the district court should deny summary judgment even if no opposing evidentiary matter is presented." *National State Bank v. Federal Reserve Bank*, 979 F.2d 1579, 1582 (3d Cir. 1992).

In following this directive, a court must take the facts in the light most favorable to the non-moving party and must draw all reasonable inferences and resolve all doubts in that party's favor. *Hugh v. Butler County Family YMCA*, 418 F.3d 265, 266 (3d Cir. 2005); *Doe v. County of Centre, Pa.,* 242 F.3d 437, 446 (3d Cir. 2001).

"A federal court sitting in diversity must apply state substantive law and federal procedural law." *Chamberlain v. Giampapa*, 210 F.3d 154, 158 (3d Cir. 2000) (citation omitted). Thus, Pennsylvania substantive law applies in this case.

B. Strict Liability Claims

In Counts I and II, Plaintiffs assert strict liability claims based upon design defect and failure to warn, respectively.

Pennsylvania law presumes that products can be the subject of strict products liability suits. *Tincher v. Omega Flex, Inc.*, 104 A.3d 328, 382, 389 (Pa. 2014) (citing Restatement (Second) of Torts § 402A, cmt. b). In 1966, the Supreme Court of Pennsylvania adopted Section 402A of the Restatement(Second) of Torts to evaluate whether a product was defective. Section 402A provides in relevant part:

> (1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if
>
> (a) the seller is engaged in the business of selling such a product, and
>
> (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.

Restatement (Second) of Torts § 402A(1); *see Webb v. Zern*, 220 A.2d 853, 854 (Pa. 1966)

(adopting Section 402A). Pennsylvania recognizes three types of defective conditions that can give rise to strict liability: design defect, manufacturing defect, and failure to warn. *Phillips v. A-Best Prods. Co.*, 665 A.2d 1167, 1170 (Pa. 1995).

Coloplast argues in its motion for summary judgment that Plaintiffs' strict liability claims fail as a matter of law because Pennsylvania product liability law does not recognize claims that are based upon prescription-only medical devices. Coloplast asserts that as interpreted and applied under Pennsylvania law, comment k to Section 402A bars strict liability claims based upon a prescription-only surgical implant such as the Aris.

Comment k to Section 402A states that:

> There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

Restatement (Second) of Torts § 402A, cmt. k (1965).

In 1996, the Pennsylvania Supreme Court applied comment k to bar strict liability failure to warn claims related to prescription drugs. *Hahn v. Richter*, 673 A.2d 888, 890 (Pa. 1996). It

has not, since then, extended its holding to prescription medical devices.

In 2006, the Pennsylvania Superior Court applied the holding in *Hahn* to prescription medical devices, stating that it could "find no reason why the same rational [sic] applicable to prescription drugs may be not be applied to medical devices." *Creazzo v. Medtronic, Inc.*, 903 A.2d 24, 27 (Pa. Super. 2006). A number of federal district courts applying Pennsylvania law have cited *Creazzo* and predicted that the Pennsylvania Supreme Court would extend comment k to exclude medical devices from strict liability claims. *See McPhee v. DePuy Orthopedics, Inc.*, 989 F. Supp. 2d 451, 460-61 (W.D. Pa. 2012); *Horsmon v. Zimmer Holdings*, 2011 WL 5509420, at *2 (W.D. Pa. Nov. 10, 2011); *Parkinson v. Guidant Corp.*, 315 F. Supp. 2d 741, 746-48 (W.D. Pa. 2004).

Since then, other courts have continued to evaluate this issue, and a number have declined to follow the holding in *Creazzo.* They have done so for several reasons. Most of the cases that cite *Creazzo* with approval predate the Pennsylvania Supreme Court's holding in *Tincher*, which cautioned courts from making categorical exemptions of immunity strict liability:

> Courts, which address evidence and arguments in individual cases, are neither positioned, nor resourced, to make the kind of policy judgments required to arrive at an *a priori* decision as to which individual products, or categories and types of products, should be exempt. Neither courts, nor the American Law Institute for that matter, are in the business of articulating general principles tailored to anoint special "winners" and "losers" among those who engage in the same type of conduct. In our view, the question of "special tort-insulated status" for certain suppliers—for example, manufacturers of innovative products with no comparable alternative design-optimally "requires an assessment and balancing of policies best left to the General Assembly."

104 A.3d at 396. As the Pennsylvania Supreme Court clarified, where no immunity from strict liability exists under the common law, or in circumstances where the Pennsylvania General Assembly has not created immunity for a specific product or category of products, "the default general rule of possible liability operates." *Id.* (quoting *Scampone v. Highland Park Care Ctr.,*

LLC, 57 A.3d 582, 599 (Pa. 2012)).

In *Lance v. Wyeth*, 85 A.3d 434, 452 n.21 (Pa. 2014), a case decided by the Pennsylvania Supreme Court the same year as *Tincher*, it noted that "this Court applied a rather one-dimensional analysis in its adoption of a blanket approach to comment k in the first instance. For example, the terse opinion in *Hahn* does not so much as mention, let alone evaluate, the reasons why many other jurisdictions had interpreted comment k to require a case-by-case assessment concerning the availability of its protections." While it made it clear that it was not revisiting *Hahn*, the court stated that "the truncated analysis in the *Hahn* line offers a poor foundation for extrapolation." *Id.*

As discussed in *Gross v. Coloplast Corp.*, 2020 WL 264691, at *4 (E.D. Pa. Jan. 17, 2020), the *Creazzo* opinion:

> in a few sentences, apparently with limited briefing, categorically extended comment k and *Hahn*'s reasoning to medical devices. But *Tincher* and *Lance* discourage Pennsylvania courts from making such categorical decisions at all, especially briefly, especially on limited records, and especially based on comment k and *Hahn*. *Creazzo*, therefore, is not persuasive authority of how the Pennsylvania Supreme Court would decide this question.

See also Schrecengost v. Coloplast Corp., 2019 WL 6465398, at *12 (W.D. Pa. Dec. 2, 2019) (noting that the pro se plaintiffs in *Creazzo* did not offer a different interpretation of *Hahn* and the Pennsylvania Supreme Court has never cited, relied on, adopted or even addressed *Creazzo*'s rationale that medical device manufacturers cannot be subject to strict liability claims).[16] *But see*

[16] In *Beard v. Johnson & Johnson, Inc.*, 41 A.3d 823 (Pa. 2012), the plaintiff brought a strict liability design defect claim against the manufacturer of a surgical tool. The Pennsylvania Supreme Court did not invoke comment k or suggest that the claim was barred on that basis. Courts have divided on how to interpret the court's silence. *Compare Schrecengost*, 2020 WL 733126, at 12 (*Beard* casts *Creazzo* into doubt) *and Wagner v. Kimberly-Clark Corp.*, 225 F. Supp. 3d 311, 317 (E.D. Pa. 2016) (predicting that the court would allow strict liability manufacturing defect claims against prescription medical device manufacturers) *with Rosenberg v. C.R. Bard, Inc.*, 387 F. Supp. 3d 572, 578 n.2 (E.D. Pa. 2019) (positing that the product at

Kohn v. Ethicon, Inc., 2020 WL 733126, at *4 (E.D. Pa. Feb. 13, 2020) (referring to those cases as "predictions" and citing other cases predicting that Pennsylvania law would not allow plaintiffs to bring strict liability claims in medical device cases).[17]

Courts continue to be divided on this issue. *Compare Rosenberg v. C.R. Bard, Inc.*, 387 F. Supp. 3d 572, 580-81 (E.D. Pa. 2019) (stating that "nothing in *Tincher* reopens the door to strict liability claims for prescription drugs or prescription medical devices, a door *Hahn* had firmly closed")[18] *with Wagner v. Kimberly-Clark Corp.*, 225 F. Supp. 3d 311, 317 n.8 (E.D. Pa. 2016) (noting that the court in *Tincher* stated that § 402A covers the sale of "any product" and then cited *Hahn*—which discussed only prescription drugs—as the only exception) *and Mills v. Ethicon, Inc.*, 406 F. Supp. 3d 363, 379 (D.N.J. 2019) (stating that "every federal district court to confront this issue has predicted that the Pennsylvania Supreme Court would extend Comment k's application to strict liability design defect and failure to warn claims related to medical devices.")

Based upon a comprehensive review of these decisions, the Court finds that the more persuasive authority are those decisions that conclude that extending comment k to medical devices is a matter that should be addressed by the Pennsylvania General Assembly or the Pennsylvania Supreme Court. Moreover, the *Creazzo* case represents less than a convincing prediction of how the Pennsylvania Supreme Court would decide the question. The *Creazzo* case

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issue in *Beard* must not have been a prescription medical device).

[17] *Gross* and *Schrecengost* specifically refused to follow *Creazzo* and apply comment k to the Aris, the pelvic mesh product at issue in this case.

[18] In addition to this sweeping statement despite the fact that the *Hahn* case did not even involve prescription medical devices, the *Rosenberg* court also analyzed the "plain language" in comment k and found "no meaningful distinction" between prescription drugs and prescription medical devices. *Id.* at 577. The Pennsylvania Supreme Court in *Tincher* indicated that neither courts nor the American Law Institute should make policy judgments that exclude whole categories of products from strict liability.

lacks any compelling reasoning, has never been cited by the Pennsylvania Supreme Court and predates that court's pronouncements in *Tincher* and *Lance* that caution against immunizing categories of products from strict liability and limit the holding in *Hahn* to prescription drugs. It should also be noted that many of the cases upon which Coloplast relies either predate *Tincher* or never mention it at all. Thus, they are not helpful to a well-reasoned analysis. Moreover, the more recent cases that dismiss *Tincher*'s comments as inapposite (either because the case concerned steel tubing or because it includes a reference to *Hahn*) are not persuasive.

Therefore, the Court declines to hold that comment k bars Plaintiffs' strict liability claims.

While Coloplast does not argue in the alternative that Plaintiffs' strict liability claims are otherwise deficient as a matter of law, the Court has reviewed the record presented by the parties and finds that genuine issues of material fact preclude summary judgment.

In order to prevail on a strict liability claim, a plaintiff must show that "the product was defective, the defect existed when it left the defendant's hands, and the defect caused the harm." *High v. Pennsy Supply, Inc.*, 154 A.3d 341, 345-46 (Pa. Super. 2017) (citation omitted). "A product may be found to be defective based on proof of any one of three conditions: a manufacturing defect in the product itself, a defect in the product's design, or a failure of the manufacturer to warn of the product's danger or to instruct on the proper use of the product." *Id.* at 346.

As explained in more detail below, Plaintiffs have offered the expert opinions of Dr. Rosenzweig, who concludes that the Aris is defectively designed, that safer alternatives existed and that Coloplast's warnings were inadequate. While Coloplast disputes his opinions, genuine issues of fact regarding these issues must be resolved by the jury.

Likewise, Dr. Campbell opines that the Aris is the cause of certain injuries and damages sustained by Plaintiffs. Coloplast contends that Plaintiffs have not produced evidence of specific causation because Dr. Campbell's opinions are unreliable and inadmissible. As explained in the Court's separate opinion which denies Coloplast's motion to exclude Dr. Campbell's testimony at trial, however, Dr. Campbell will be permitted to offer expert testimony at trial, other than as to those opinions which he has withdrawn. Therefore, Plaintiffs have proffered sufficient evidence that the Aris was the cause of their injuries and damages.

Therefore, with respect to the strict liability claims in Counts I and II of the Complaint, Coloplast's motion for summary judgment will be denied.

C. Negligence Claims

In Count III, Mrs. Moultrie alleges that Coloplast negligently designed the Aris and failed to warn of the risks associated with its use. In its motion for summary judgment, Coloplast argues that Plaintiffs have offered no evidence that Coloplast failed to exercise reasonable care in designing the Aris. They further contend that the failure to warn claim is barred by the learned intermediary doctrine.

"It is axiomatic that in order to maintain a negligence action, the plaintiff must show that the defendant had a duty 'to conform to a certain standard of conduct;' that the defendant breached that duty; that such breach caused the injury in question; and actual loss or damage." *Phillips v. Cricket Lighters*, 841 A.2d 1000, 1008 (Pa. 2003) (citation omitted). Expert evidence is "generally required in a products liability case where a defect is alleged," unless the "matter under consideration is simple and lack of ordinary care is obvious and within the range of comprehension of the average juror." *Oddi v. Ford Motor Co.*, 234 F.3d 136, 159 (3d Cir. 2000). The parties do not dispute that expert evidence is required in this case.

Plaintiffs must demonstrate that the Aris "is capable of causing" Mrs. Moultrie's alleged injuries (general causation) and that in her particular case, that it "did in fact cause them." *Soldo v. Sandoz Pharms. Corp.*, 244 F. Supp. 2d 434, 576-77 (W.D. Pa. 2003) (citations omitted) (specific causation).

Negligent Design Claim

Plaintiffs contend that the Aris was negligently designed and through expert analysis, have identified safer and available alternatives that would have reduced or eliminated Mrs. Moultrie's injuries (lighter-weight, large-pore mesh designs). At the same time, they also contend that they do not have to point to safer alternatives in order to support their claim. Coloplast argues that Plaintiffs' alternatives are substantially different products and therefore cannot sustain their claim.

In *Lance*, the Pennsylvania Supreme Court rejected the defendant's argument that it "required proof of an alternative safer design as an absolute prerequisite to the advancement of a design-defect claim." 85 A.3d at 458 n.36. Rather, plaintiffs "who have premised their own liability cases on the availability of an alternative safer design need to prove their claim on its own terms in order to succeed." *Id.*[19]

Dr. Rosenzweig explains in his report that lighter weight, large-pore mesh designs would have decreased the chronic foreign body reaction, fibrotic bridging, and erosion problems associated with smaller pore, heavier weight polypropylene mesh, such as that used in the Aris.

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[19] Coloplast relies on *Salvio v. Amgen, Inc.*, 810 F. Supp. 2d 745, 754 (W.D. Pa. 2011), in which the court dismissed a negligent design claim because the plaintiff merely asserted that an alternative treatment regimen was safer than the product at issue without further detail or support. *See also Bell*, 2018 WL 2447788, at *5 (plaintiff failed to allege any alternative ways in which the product could have been designed, failed to allege how the product was defective and failed to allege any facts to show that a reasonable alternative design could have been practically adopted). In this case, however, Plaintiffs have produced evidence and expert opinions in support of their claim that feasible alternative designs to the Aris existed.

Plaintiffs have proffered evidence that Coloplast knew that lighter weight mesh alternatives existed prior to 2008 and was warned about the use of heavier weight mesh and its relationship to increased erosion rates but ignored such warnings. This expert evidence creates issues of fact that must be presented to the trier of fact to determine if the Aris was negligently designed.

In addition, although Plaintiffs are not required to identify a specific device that presented a safer alternative, they have done so. Dr. Rosenzweig referenced the lighter-weight, large-pore mesh design used in Ultrapro as such a feasible alternative. Coloplast contends that because the Ultrapro has not been indicated for surgical treatment of SUI or cleared by the FDA for this purpose, Plaintiffs cannot proffer it as a safer alternative to the Aris. However, Coloplast's argument that the reasonable alternative must be one that "could have been practically adopted" by the manufacturer at the time of sale traces back to a statement in *Hoffman v. Paper Converting Mach. Co.*, 694 F. Supp. 2d 359, 366 (E.D. Pa. Mar. 3, 2010), in which that court: 1) relied upon the Restatement Third's formulation of product liability, which the Pennsylvania Supreme Court subsequently indicated that it would not adopt; and 2) stated that if the plaintiff produces expert testimony that a reasonable design alternative could have been practically adopted, a trier of fact may conclude that the product was defective, even if it was not adopted by any manufacturer or even considered for commercial use at the time of sale. Thus, the lack of FDA approval would not be dispositive of the issue even under a Restatement (Third) approach.[20]

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[20] Dr. Rosenzweig also cites three other alternatives, at least two of which (the autologous fascia sling and the Burch colposuspension) appear to be surgical procedures rather than medical devices. While Dr. Rosenzweig testified that "a suture is a medical device," he did not address the issue of how Coloplast could have "modified" its Aris device by abandoning it altogether in favor of a surgical procedure, a position that, as Coloplast argues, appears to address the medical judgment of the treating physician rather than the design decisions made by the manufacturer. *See Mullins v. Johnson & Johnson*, 236 F. Supp. 3d 940, 943 (S.D. W.Va. 2017) (evidence that a

Simply put, genuine issues of material fact exist regarding Plaintiffs' claim of negligent design.

Negligent Failure to Warn Claim

"In the duty to warn context, assuming that plaintiffs have established both duty and a failure to warn, plaintiffs must further establish proximate causation by showing that had defendant issue a proper warning to the learned intermediary, he would have altered his behavior and the injury would have been avoided." *Demmler v. SmithKline Beecham Corp.*, 671 A.2d 1151, 1155 (Pa. Super. 1996) (citation omitted), *appeal denied*, 684 A.2d 557 (Pa. 1996). *See also Soufflas v Zimmer*, 474 F. Supp. 2d 737, 754 (E.D. Pa. 2007).

Pursuant to the learned intermediary doctrine, a manufacturer will be held liable only when it fails to adequately warn the intended user, which in the case of prescription drugs or medical devices, is the physician and not the patient. *Parkinson v. Guidant Corp.*, 315 F. Supp. 2d 741, 748 (W.D. Pa. 2004); *Rosci v. AcroMed, Inc.*, 669 A.2d 959, 969 (Pa. Super. 1995). Whether a warning is adequate depends on whether the learned intermediary, having considered "the data supplied to him by the manufacturer, other medical literature, and any other sources available to him, and weighing that knowledge against the personal medical history of his patient," would use his independent judgment to prescribe a medical device. *Coyle v. Richardson-Merrell, Inc.*, 584 A.2d 1383, 1386 (Pa. 1991).

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surgical procedure should have been used in place of a pelvic mesh device did not present an alternative feasible design because it would not inform the jury on how the device at issue could have been made safer to eliminate the risks that caused the plaintiff's injuries); *Talley v. Danek Med., Inc.*, 179 F.3d 154, 162 (4th Cir. 1999) (expert's testimony that spinal fixation screws were defective because spinal procedures with the screws were not more successful than such procedures without the screws did not indicate a design flaw, but questioned the medical judgment of the doctor who used the screws); *Theriot v. Danek Med., Inc.*, 168 F.3d 253, 255 (5th Cir. 1999) (the fact that other products that did not use pedicle screws might be safer challenged the choice of treatment of the plaintiff's doctor, not the design of the product).

In *Demmler*, the court granted summary judgment on a failure to warn claim because the plaintiff failed to present evidence that a more thorough or explicit warning would have prevented her use of the product or that a different warning would have altered her use of the product in accordance with her doctor's instructions. 671 A.2d at 1155-56. In particular, the plaintiff sought a warning not about the product at issue, but about another drug that was usable as an antidote to the hypertensive crisis the plaintiff suffered, but the court held that the plaintiff failed to point to evidence of sufficient weight to establish a reasonable likelihood that a more thorough or explicit warning would have prevented her use of the drug at issue.

On the other hand, courts have denied summary judgment when presented with evidence that the plaintiff's prescribing physicians had been unaware of the risk of injury and would have acted differently had he or she been aware of that risk. *See Simon v. Wyeth Pharms., Inc.*, 989 A.2d 356, 375 (Pa. Super. 2009); *Daniel v. Wyeth Pharms., Inc.*, 15 A.3d 909, 925 (Pa. Super. 2011); *Rowland v. Novartis Pharm. Corp.*, 34 F. Supp. 3d 556, 574-77 (W.D. Pa. 2014). [21]

Coloplast contends that because Dr. David did not review or rely upon the IFU prior to Mrs. Moultrie's surgery, her failure to warn claim is barred by the learned intermediary doctrine. If he did not read the warning, they argue, no amount of additional warning would have made a difference. In support, they cite *Burton v. Danek Medical, Inc.*, 1999 WL 118020, at *8 (E.D. Pa. Mar. 1, 1999), in which the court granted summary judgment for the manufacturer because the plaintiff offered no expert testimony that the warning was inadequate.

In this case, Plaintiffs have proffered expert testimony that the warning was inadequate. Moreover, Dr. David had reviewed the IFU at some point prior to Mrs. Moultrie's surgery; while

[21] In *Bock v. Novartis Pharms. Corp.*, 137 F. Supp. 3d 802 (W.D. Pa. 2015), Chief Judge Hornak reached a different result because in that case, Plaintiff's physicians were aware of the risk of the drug at the time and indicated that they still prescribe the drug today. In addition, there was no evidence that plaintiff would have declined use of the drug if he had been told about the risk.

it was years before, no evidence was offered by Coloplast that the warnings were modified in the interim. He testified that he was bothered by the general warnings in the IFU, which did not address the specific risks associated with the Aris sling, and was not warned that permanent dyspareunia could result. If Coloplast had communicated percentages of risks on the various complications that could occur, Dr. David would have presented those percentages to his patients, including Mrs. Moultrie, so that she could make an informed decision. Further, Mrs. Moultrie would not have agreed to have the Aris implanted had she known of the risks of permanent vaginal pain, permanent pelvic pain and permanent dyspareunia.

Thus, Coloplast's argument is unavailing. With respect to Count III, the motion for summary judgment will be denied.

D. Loss of Consortium

Finally, Coloplast has also moved for summary judgment with respect to Mr. Moultrie's claim in Count XIV for loss of consortium. A loss of consortium claim is considered to be derivative of the injured spouse's right to recovery. *See Scattaregia v. Shin Shen Wu*, 495 A.2d 552, 553-54 (Pa. Super. 1985). Thus, if judgment was granted in favor of Coloplast with respect to all of Mrs. Moultrie's claims, Coloplast would also be entitled to judgment in its favor on Mr. Moultrie's derivative claim. *See Pusey v. Becton Dickinson & Co.*, 794 F. Supp. 2d 551, 565-66 (E.D. Pa. 2011).

Because Coloplast's motion for summary judgment regarding Mrs. Moultrie's claims will be denied, however, it will also be denied regarding Mr. Moultrie's derivative claim in Count XIV.

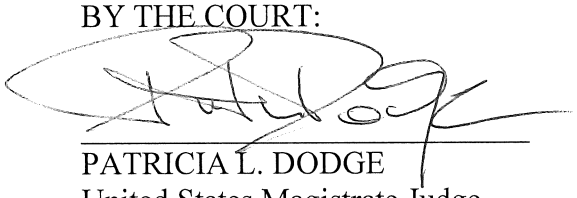
IV. Conclusion

For the reasons discussed above, Coloplast's motion for summary judgment will be granted only with respect to the manufacturing defect claims asserted in Count I and III, and otherwise will be denied.

An appropriate order follows.

March 16, 2020

BY THE COURT:



PATRICIA L. DODGE
United States Magistrate Judge